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APPLICATION NO. 350	FILING DATE 11/99	FIRST NAMED INVENTOR TATTON	ATTORNEY DOCKET NO. WTZ-004
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000959

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HM12/1023

EXAMINER BAHAR, M
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ART UNIT 1617	PAPER NUMBER 14
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DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/249,350

Applicant(s)

TATTON ET AL.

Examiner

Mojdeh Bahar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's response to the previous office action of 27 March 2001, amendment and remarks submitted September 27, 2001 (Paper No. 13) is acknowledged. Claims 1-8 are herein examined on the merits.

Newly submitted claims 24-29 directed to a specie of virus that is independent or distinct from the specie originally elected for the following reasons: In response to the Election/Restriction requirement of December 19, 2000, applicant elected to prosecute HIV as the specie. Accordingly, claims 24-29 are withdrawn from consideration as being directed to non-elected species.

The claims are examined herein to the extent they read on the elected species.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "such that treatment of the viral infection occurs by inhibiting replication of a virus in a virus infected cell" renders the claims indefinite in scope as to administration conditions in which treatment by inhibition of the viral replication occurs in a virus infected cell.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatton et al. (WO 97/28791, reference D1 in the IDS filed December 13, 1999) in view of Meulen et al. (DE 19708461; English abstract provided, reference D2 in the IDS filed December 13, 1999) and Tatton et al. (Neurology, 1996, reference CB in the IDS filed June 21, 1999), of record in the previous office action.

Tatton et al. (WO 97/28791) teaches a method of using deprenyl compounds in general and (-)-desmethyldoprenyl in particular to treat viral infections, (page 9, lines 15-20 and page 10, lines 25-26). Tatton et al. (WO 97/28791) also teaches a pharmaceutically acceptable carrier (page 15, lines 5-20) as well as transdermal patches as a method of administering (-)-desmethyldoprenyl (page 19, lines 17-25).

Tatton et al. (WO 97/28791) does not expressly teach the employment of (-)-desmethyldoprenyl particularly, in a method of treating HIV. Neither does it teach the treatment of a viral infection through the inhibition of virus replication.

Meulen et al. (DE 19708461) teaches a method of treating viral infections of the central nervous system employing D-Methyl Seligilin (a deprenyl compound), see abstract. Meulen et al. (DE 19708461) also teaches HIV as one of the infections in which the method would be effective, Col. 1, lines 51-55.

Tatton et al. teaches a method of using (-)-desmethyldoprenyl as a mediator of antiapoptotic action, see abstract, page 171. Tatton et al. also teaches that AIDS Protein has been shown to induce apoptosis (p174 col.2).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use (-)-desmethyldeprenyl, a known antiapoptotic agent, in the treatment of HIV viral infection since HIV protein is known to induce apoptosis.

One of ordinary skill in the art would have been motivated to use the deprenyl compound, (-)-desmethyldeprenyl in the treatment of HIV because (1) it is a known antiapoptotic agent and (2) is suggested to have antiviral activity. Given that AIDS protein has been known to induce apoptosis, an antiapoptotic agent would be useful in antagonizing the AIDS (HIV) virus protein activity. Moreover, the Skilled Artisan would have been motivated to employ a compound that is suggested to have antiviral activity broadly in a method of treating the HIV viral infection in particular, absent evidence to the contrary. No such evidence is seen. Note that the treatment of a viral infection through the inhibition of virus replication is seen to be a mere recitation of the mechanism of action of the claimed method. Further, note that recitation of a mechanism of action by itself, will not patentably distinguish the claimed invention from the prior art which clearly suggests the usefulness of the elected compound herein in a method of treatment for HIV infection.

### ***Response to Arguments***

In the remarks submitted September 27, 2001, applicants argue that the cited prior art does not teach, nor suggests “a method of treating viral infection by inhibiting replication of a virus in virus infected cells”. Applicant’s argument in this regard has been considered but is not persuasive. Applicant’s argument is based on the mechanism of antiviral action herein. The underlined portion, “inhibition of virus replication”, indicates nothing more than the mechanism of action through which viral replication is inhibited. The recitation of the mechanism of action

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by itself will not patentably distinguish the instant invention from the cited prior art which clearly suggests antiviral anti-HIV activity for the elected compound herein. Note that the instant method requires administering to a subject a therapeutically effective amount of a deprenyl compound. The prior art also teaches administering to a subject a deprenyl compound. Therefore the viral replication inhibition would be expected to have occurred in the prior art method. More specifically, the prior art teaches a method of treating viral infections by employing a deprenyl compound in therapeutic antiviral amounts. The prior art further teaches that the deprenyl compound is used in treating HIV particularly. Therefore as set forth in the obviousness rejection herein above the prior art suggests the employment of the elected deprenyl compound herein in the instant method of treating HIV infection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

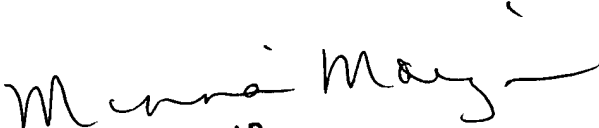
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
October 16, 2001

  
MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600